DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, New York 14202

M3647n

April 6, 2000

**WARNING LETTER NYK 2000-57**

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David A. Unger
Box 10, Smith Road
Hamilton, New York 13466

Dear Mr. Unger:

An inspection of your cattle dealership and dairy operation located in Hamilton, New York was conducted by a Food and Drug Administration investigator on January 13, 25 and 27, 2000. This inspection confirmed a cow you purchased and subsequently sold on or about June 16, 1999, for slaughter for human food was in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug and Cosmetic Act (the Act). USDA analysis of tissue samples collected from that animal identified the presence of 11.00 parts per million (ppm) sulfamethazine. The extralabel use of sulfamethazine in lactating animals is prohibited under 21 CFR 530.41. Therefore, there is no permitted level of sulfamethazine in lactating dairy animals. The presence of sulfamethazine in liver tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

You also offered two cows for slaughter as human food on consignment for [redacted] and [redacted] that were adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. You offered the first cow identified with ear tag [redacted] on or about March 8, 1999. The cow was slaughtered on March 11, 1999 at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 2.70 ppm gentamicin. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. You offered the second cow identified with ear tag [redacted] on or about October 13, 1999. The cow was slaughtered on October 14, 1999 at [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of 2.90 ppm gentamicin. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice such as seizure and/or injunction.

You should not consider this to be an all-inclusive list of the violations existing at your facility. It is your responsibility to assure your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take the following precautions:

1. Implement a system to identify the animals you purchase with records to establish traceability to the source of the animal.

2. Implement a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3. If the animal has been medicated, implement a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact you offered an animal for sale and it was subsequently offered for sale to a slaughterhouse, which ships in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,

Brenda J. Holman
District Director